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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

Background- Hot flashes, and other symptoms of estrogen withdrawal, are common in breast cancer survivors. The standard treatment for these symptoms, hormone replacement therapy, is contraindicated in breast cancer survivors. Homeopathic medicines have been used to treat hot flashes and other menopausal symptoms for more than 100 years.
Objectives- To carry out a pilot study to determine whether there is evidence that homeopathy is an effective treatment to improve the quality of life in breast cancer survivors who are experiencing hot flashes and other menopausal-type symptoms.
Methods- A randomized double-blind placebo controlled trial is being carried out in a group of 83 breast cancer survivors with hot flashes and other menopausal symptoms. Subjects were recruited from the Comprehensive Breast Center at Providence Hospital in Seattle and other affiliated clinics. Subjects have a history of hot flashes for at least one month, with at least 3 hot flashes per day. Subjects have been randomized to one of three treatment arms: classical homeopathy, a combination homeopathic remedy, or placebo. Number of hot flashes, general health status, patient satisfaction, and health care utilization services are being measured over a period of 12 months.
Results/Significance- Data collection is not complete, so there are no results at this time.

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INTRODUCTION

Hot flashes, and other symptoms of estrogen withdrawal, are common in both pre- and post-menopausal breast cancer survivors. The standard treatment for these symptoms, hormone replacement therapy, is contraindicated in breast cancer survivors due to fear that it will stimulate tumor growth. Homeopathic medicines have been used to treat hot flashes and other menopausal symptoms for more than 100 years. Our goal is to determine whether homeopathy is an effective treatment to improve the quality of life in breast cancer survivors who are experiencing hot flashes and other menopausal-type symptoms. We plan to do a pilot study that demonstrates our ability to successfully conduct a full-scale trial. A randomized double-blind placebo controlled trial will be carried out in a group of 105 breast cancer survivors with hot flashes and other menopausal symptoms. Subjects will be randomized to one of three treatment arms: classical homeopathy, a combination homeopathic remedy, or placebo. Number of hot flashes, menopausal index scores, general health status, patient satisfaction, and the use of health care services will be measured over a period of 12 months.

BODY

Research Accomplishments

The following research accomplishments have been achieved in the second year of the study. No statistical tests have been carried out or findings presented as we are still in the data collection phase of the study and the randomization code has not been broken.

Task 2. Enrollment of Subjects

a. Eligibility of prospective subjects was confirmed at screening appointments, informed consent was confirmed, and baseline questionnaire data was collected
b. An additional 29 subjects were enrolled between September, 2000 and March 2001 for a total of 83 patients enrolled in the study. The recruitment period was extended and to recruit patients from Swedish Medical Center, which recently acquired Providence Medical Center, where the initial subjects were recruited.
c. Initial homeopathic consultation and randomization of subjects to one of three treatment groups has been carried out on all 83 subjects. Medicines have been mailed to all subjects according to the protocol schedule.
d. Telephone interviews have been conducted at 1 (83 subjects), 2 (76 subjects), and 3 (71 subjects) months after randomization to assess progress and collect outcomes information. Hot flash diaries have been mailed and collected for the week prior to each of these calls.
e. Follow-up homeopathic consultations have been conducted at 2 (76 subjects and 4 (68 subjects) months after the initial homeopathic visit.
f. Data entry of initial consultations and follow-up visits has been done as they occur, as well as the information collected during telephone interviews.

Task 3. Patient Follow-up

a. Telephone interviews at 6 (62 subjects) and 9 (58 subjects) months after randomization have been conducted to assess progress and collect outcomes information. Hot flash diaries have been mailed and collected for the week prior to each of these calls.
b. Follow-up homeopathic consultations at 6 (62 subjects), 8 (58 subjects), 10 (40 subjects), and 12 (26 subjects) months after the initial homeopathic visit have been conducted.
c. Data entry of follow-up visits has continued as they occur, as well as information collected during telephone interviews.
d. Annual report for Years I and II have been prepared.

Research Challenges

Our biggest challenges have been in a) recruitment and b) retention of study subjects. Patient recruitment was slower than anticipated and we were unable to recruit our target number of subjects. We addressed this problem by expanding recruitment to potential subjects from Swedish Medical Center, which recently acquired Providence Medical Center, the facility from which initial subjects were recruited. We extended the recruitment period for an additional seven months through March, 2001, to obtain a total of 83 patients in the study, 79% of our projected cohort of 105. At that point, we ended enrollment, in order to complete the 12 months of follow-up for all patients by the end of the grant period of March 2002.

Withdrawals have also been higher than anticipated, with a total of 27 withdrawals from the study (32.5%) by the end of August, 2001. These can be summarized as follows:

Month withdrawing	Number of participants
1	7
2	5
3	3
4	2
6	5
8	3
10	2
Total withdrawals	27

Reasons for withdrawals have varied. There were 12 (44%), who reported no relief from hot flashes, 6 (22%) had a cancer recurrence or were advised to withdraw by their physicians because of the need for additional medications, 5 (18.5%) said the study was too inconvenient, and 4 (15%) were lost to follow-up. However, 66 of the 83 originally enrolled completed at least six months of the study (80%), so there should be

adequate data for meaningful analysis. We also intend to look at the withdrawal rate by study arm to see whether those receiving placebo had a higher withdrawal rate.

Another area that has been problematic is in the use of three study arms: classical homeopathy, a combination homeopathic medicine, and placebo. Because of this design, we have used a "double-dummy" design, whereby all subjects are taking two types of medicines, one or both of which might be placebo. This has been confusing to many subjects as well as to the homeopathic prescribers, who have difficulty making treatment decisions because of the uncertainty as to which treatment group a patient might be assigned.

Future Recommendations

Although the data collection phase of the project is incomplete, we have enough experience at this point to make the following recommendations for future studies in this area:

1. Recruitment needs to be more aggressive, with a larger budget that would allow for advertisements in the local media and also a stipend or gift incentive for the study participants.
2. The study period should be shortened to six months, as this seems long enough to determine treatment success. It is unreasonable to expect women who are receiving a placebo to continue for one year with no improvement in their symptoms.
3. Elimination of the double-dummy design and testing only one arm against placebo. This would make treatment decisions for the homeopathic prescribers more customary to what they experience in actual practice.

KEY RESEARCH ACCOMPLISHMENTS

None so far as we are still in the data collection phase of this study

REPORTABLE OUTCOMES

None

CONCLUSIONS

Because the data collection is incomplete, it is too soon to make any conclusions. We have found several areas of difficulty, including recruitment, retention, and implementation of the double-dummy design and would recommend that additional strategies be used in future studies to address these problems.

REFERENCES/APPENDICES

None